

REMARKS

Claims 1-5, 9 and 18 are currently pending. Claims 7, 8 and 10-17 are canceled without prejudice. Support for new Claim 18 is founding original Claim 6. Support for new Claim 19 can be found in original Claim 1 and page 6, lines 5-8 of the specification as filed. Support for Claim 20 can be found in original Claim 1. No new matter has been added herewith. The following addresses the substance of the Office Action

Claim Objections

Claims 13-15 were objected to under 35 U.S.C. § 1.75(c) as being in improper form because a multiple dependent claim should refer to other claims in the alternative only. Since these claims were omnibus claims, which are not allowable in the U.S., they are canceled.

Claim 3 was objected to because of the term "or" at line 5. Applicants have amended the claim to use Markush language, including the term "and" before the last recited process.

Utility

Claims 4-5 were rejected under 35 U.S.C. § 101, because the claimed recitation of a use, without setting forth any steps involved in the process, results in an improper process claim under 35 U.S.C. § 101. The claims are amended to set forth the step of administering to a subject an isolated extract. Accordingly, the claims are in compliance with 35 U.S.C. § 101 and removal of the rejection is respectfully requested.

Indefiniteness

Claims 1-12 and 16-17 were rejected under 35 U.S.C. § 112, second paragraph as being indefinite.

Claim 1: the Examiner regards claim 1 as being unclear as there is no lower limit to the molecular weight and it does not make sense to have components having a molecular weight of 0 kDa. Applicants have amended Claim 1 to recite that the extract contains components having a molecular weight, wherein said molecular weight is less than or equal to 10 kDa. Since the components must have a molecular weight, and as indicated by the Examiner, 0 kDa is not a theoretically possible molecular weight, the claim now excludes the possibility of a molecular weight of 0 kDa..

The Examiner objected to the use of the term "proliferative effect" in Claim 1 on the basis that it is unclear what a proliferative effect is. Applicants have amended Claims 1 and 3 to recite

that the components induce proliferation of endothelial cells. A person skilled in the art will understand the term "proliferation" as referring to the growth and replication of cells.

The Examiner objected to the use of the term "substantially" in Claims 1 and 3 on the basis the word "substantially" is a relative term which renders the scope of the claims indefinite. Applicants have removed the term "substantially" from Claim 1 and have substituted with the term "about" in Claim 3. Referring to MPEP 2173.05(b), when a term of degree is presented in a claim, first a determination is to be made as to whether the specification provides some standard for measuring that degree. If it does not, a determination is made as to whether one of ordinary skill in the art, in view of the prior art and the status of the art, would be nevertheless reasonably apprised of the scope of the invention. In this case, one of skill in the art would expect that the recited heating temperature and length of heating time would encompass ranges within reason, particularly since the processes recited would likely be carried out with imperfect precision by the experimentalist.

The Examiner objected to the clarity of Claim 3. Applicants have amended Claim 3 to clearly recite that the components are prepared by being subjected to at least one process selected from the group consisting of heating to about 100°C for up to about 3 minutes; sterilization by exposure to over 2.5 Mrads of γ -irradiation; and freeze thawing. Claim 3 distinguishes over Claims 1 and 2 since Claims 1 and 2 does not contain the limitation of the components being subjected to at least one of the processes recited in Claim 3. This limitation is not inherently present, nor alluded to, in Claims 1 and 2, which make no reference to further processing of the extract. The processing according to Claim 3 may lead to a limited set of components compared to the components present in an isolated extract defined by Claims 1 and 2.

The Examiner objected to Claim 6 on the basis it is unclear how free amino acids, lipids or carbohydrates have a proliferative effect on endothelial cells. Applicants have amended Claim 6 to clarify that the free amino acids, lipids or carbohydrates do not necessarily have any effects on endothelial cells.

The Examiner has objected to claims 7 and 8 on the basis it is unclear how the claims further limit claim 1. Applicants have canceled claims 7 and 8, thereby rendering the rejection moot.

Claims 2, 4-6, 9-12 and 16-17 were rejected as depending from the aforementioned claims. In light of the amendments to the claims discussed above, Claims 2, 4, 5 and 9 are in compliance with 35 U.S.C. § 112, second paragraph and Claims 11, 12, 16 and 17 are canceled.

Anticipation

Claims 1-12 and 16-17 were rejected under 35 U.S.C. § 102(b) as being anticipated by Weng et al. (2001 *Acta Pharmaceutica Sinica* **36**(11):817-820). The Examiner notes that the reference teaches that total velvet antler polypeptides (TVAP) accelerated skin wound healing by stimulating proliferation of epidermal cells. However, proliferation of epidermal cells, as taught by Weng et al. does not mean that the proliferation of endothelial cells is affected, as claimed. Nothing disclosed in Weng et al. suggests that TVAP will induce proliferation of endothelial cells and/or promote angiogenesis.

Weng et al. discloses that polypeptides extracted from velvet antler promote proliferation of fibroblasts, cartilage cells and epidermal cells. Fibroblasts are not endothelial cells, and cartilage cells are entirely irrelevant for skin wound healing. Moreover, epidermal cells are not involved in angiogenesis. The Applicants note that factors that promote growth of epidermal cells will not necessarily promote growth of endothelial cells (as per the present claims).

Skin wound healing and angiogenesis are related. Kapoor et al. 2004 *Am J Pathol* **165**:299-307 (attached herewith) reports at page 299, the first paragraph following the abstract that "wound healing is a complex pathophysiological process involving interplay of several cellular and biochemical processes. This highly complex phenomenon includes the interaction of inflammation, re-epithelialization, angiogenesis, granulation tissue formation and collagen deposition". Thus, endothelial cell proliferation and angiogenesis are both important processes involved in wound healing.

The presently claimed subject matter discloses an isolated extract of deer velvet which contains components which have a molecular weight, wherein said molecular weight is less than about 10 kDa and which induce proliferation of endothelial cells and/or promote angiogenesis. The cited reference discloses an extract that can promote proliferation of epidermal cells, cartilage cells and fibroblasts. There is no disclosure in the cited reference that this extract has any effect on endothelial cell proliferation or promotion of angiogenesis. As such, the extract disclosed in the cited reference cannot be said to read on the claimed extract, as it would not

necessarily have the recited characteristics. Accordingly, the Applicants respectfully request removal of the rejection.

Additionally, Applicants wish to note that newly added Claims 19 and 20 are clearly novel over the disclosure of the cited reference, which contains neither a disclosure nor a suggestion of the methods recited in these claims.

Objection Relating to Duplicative Claims

The Examiner stated that, should claims 1, 2, 4 and 9-10 be found allowable, claims 3, 5, 7, 8, 11 and 16 would be objected to as being substantially duplicative thereof.

As discussed above, Claim 3 distinguishes over Claims 1 and 2 since Claims 1 and 2 does not contain the limitation of the components having been subjected to at least one of the processes recited in Claim 3. In relation to Claim 5, it would be well known to a person skilled in the art that persistent wounds are a specific subclass of wounds and thus are not identical to the general class of wounds covered by claim 4. Claims 7, 8, 11 and 16 are canceled.

No Disclaimers or Disavowals

Although the present communication may include alterations to the application or claims, or characterizations of claim scope or referenced art, Applicant is not conceding in this application that previously pending claims are not patentable over the cited references. Rather, any alterations or characterizations are being made to facilitate expeditious prosecution of this application. Applicant reserves the right to pursue at a later date any previously pending or other broader or narrower claims that capture any subject matter supported by the present disclosure, including subject matter found to be specifically disclaimed herein or by any prior prosecution. Accordingly, reviewers of this or any parent, child or related prosecution history shall not reasonably infer that Applicant has made any disclaimers or disavowals of any subject matter supported by the present application.

Co-Pending Applications of Assignee

Applicant wishes to draw the Examiner's attention to the following co-pending applications of the present application's assignee.

Serial Number	Title	Filed
10/546,123	LOW MOLECULAR WEIGHT EXTRACTION PROCESS	22-May-2006

CONCLUSION

In view of Applicants' amendments to the Specification and the Claims and the foregoing Remarks, it is respectfully submitted that the present application is in condition for allowance. Should the Examiner have any remaining concerns which might prevent the prompt allowance of the application, the Examiner is respectfully invited to contact the undersigned at the telephone number appearing below.

Please charge any additional fees, including any fees for additional extension of time, or credit overpayment to Deposit Account No. 11-1410.

Respectfully submitted,

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